

## **REMARKS**

The issues outstanding in the office action mailed June 1, 2007, are the requirement for a substitute specification and the rejections under 35 U.S.C. §112 and §103. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

### **Specification**

Applicants have reviewed the Specification as requested, and revised the grammar as necessary. A substitute specification with markings and a clean version are provided herewith. While the examiner is thanked for the helpful suggestions at pages 3 and 4 of the Office Action, not all the paragraphs noted therein appear to need significant grammatical revision. Accordingly, if the examiner desires any further changes, specific suggestions would be appreciated. Withdrawal of the objection to the Specification is respectfully requested.

### **Rejections under 35 U.S.C. §112**

Claims 2 and 4-11 have been rejected under 35 U.S.C. §112, second paragraph. Reconsideration of this rejection is respectfully requested.

It is argued, at page 4 of the Office Action, that "decellularization" is not defined in the specification. It is moreover argued that it is unclear whether decellularization refers to a removal of a certain amount of cells or the loss of a single cell. See paragraph 12 at page 4 of the Office Action. It is respectfully submitted, contrary to the indication in the Office Action, that "decellularization" has a well known meaning in the art. For example, see U.S. Patent 5,336, 616 (provided herewith) wherein decellularization is defined as processing to remove antigenic cellular components. See column 9, line 37 through column 10, line 2. See also *Zeltinger et al.*, "Development and Characterization of Tissue-Engineered Aortic Valves," *Tissue Engineering*, 7(1) 2001, pages 9-22, and particularly the discussion of cell extraction at page 10 and 11. It is submitted to be clear that "decellularization" is well understood to one of ordinary skill in the art, and is no way indefinite. Withdrawal of this rejection is thus respectfully requested.

Claim 10 has been revised to address the criticism bridging pages 4 and 5 of the Office Action, where it is argued that the method reads on a process wherein radiation with microwaves does not require immersion in a treating solution. Casting of the claim as a one-step claim is

believed to obviate any perceived confusion. Withdrawal of this rejection is thus also respectfully requested.

**Rejection under 35 U.S.C. §103**

Claims 2, 5, 7-8 and 10-11 have been rejected under 35 U.S.C. §103 over Giberson et al., taken with Anderson '216. Reconsideration of this rejection is respectfully requested.

At the outset, it is argued at page 7 of the Office Action that the preamble (a method of decellularizing native tissue) bears no patentable weight. Regardless of any accuracy of this assertion, it is noted that Claim 10 recites that "said tissue is decellurized." It is submitted that the preamble issue is thus of no importance.

Giberson teaches fixation of tissue, e.g., with a solution containing formalin. As is well understood in the art, "fixation" does not remove any component from the tissue, but preserves the tissue as such. Clearly, the reference does not teach decellularization as the term is understood in the art, i.e., rupturing cells and removing cellular membranes, nucleic acids, lipids and/or pseudoplastinic components so as to produce materials comprised of extracellular matrix of the tissue. See, for example, Livesey '616.

Anderson, disclosing tissue welding, also does not suggest decellularization, either alone or in combination with Giberson. Tissue welding also preserves the tissue, as would be desirable, even necessary, in order to achieve the goals of Anderson, i.e., promoting wound healing. See column 1, lines 13-16, and column 2, lines 19-22, where it is noted that it is necessary to limit tissue damage such as denaturation.

It is also noted that there is an apparent misconception, for example, at page 8 of the Office Action, where it is argued that the treating solution of the present invention comprises fixing reagents. Apparently, the examiner is confused with an alternate embodiment of the invention. The present claims are directed to decellularization, not to fixing, and require a detergent which is a decellularization agent, which would be clearly contraindicated in Anderson. Accordingly, withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

It is accordingly respectfully submitted that the claims in the application are submitted to be in condition for allowance, and passage to issue is respectfully requested. However, if the examiner has any questions or comments, he or she is cordially invited to telephone the

undersigned at the number below.

No fee is believed due with this response, however, the Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402. Respectfully submitted,

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Attorney Docket No.: AKA-0286

Date: September 4, 2007

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